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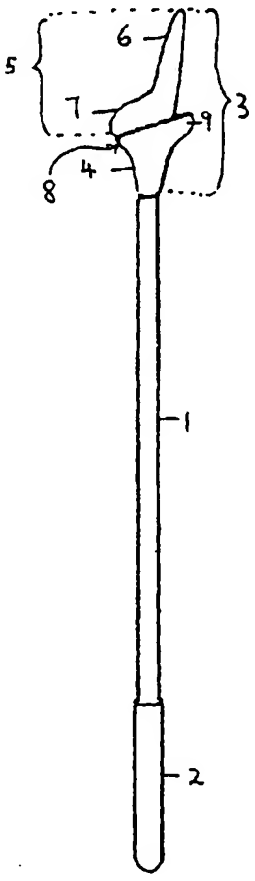
[Continued on next page]

(54) Title: ~~PRECISION CONTOURED EXO/ENDOCERVICAL CELL SAMPLER~~



(57) Abstract: An L-shaped, precision contoured EXO/ENDOcervical cell sampler for collecting representative cells is invented for pre-malignant and malignant diagnosis. The said cell sampler comprises of an elongated and rounded stick shaped stem with a slightly thickened handle means at one end, and a flattened connecting means havig two protrusions at the other end. An L-shaped configuration at the root of said connecting means has one vertical ENDOcervical contact portion and one horizontal EXOcervical contact portion, which directly hug to the transformation zone thereby allowing a through and complete 360 DEG rotatinal sweeping-up of all the truly representatives cells. When said cell sampler is withdrawn from the cervix, the vertical ENDOcervical contact portion is subsequently bent and both the EXO-and ENDOcervical portions are swept across a microscope slide for cytological microscopic examination.

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Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Precision contoured EXO/ENDOcervical cell sampler

Field of Invention

The invention relates to a specific device for collecting representative cell samples from exocervix and endocervix for cytological microscopic examination, particularly for the purpose of pre-malignant and malignant diagnosis.

Background of the Invention

Occurrence of uterine cervical cancer is high among women and the rate has been increasing. The disease becomes the main cause of cancer death among women in Malaysia. Of vital important, women are advised to have periodical medical pelvic examinations for early detection and prevention of uterine cervical cancer.

Many devices have been invented for sampling of representative cells from the uterine endocervix and exocervix for the purpose of pre-malignant and malignant diagnosis. Such devices are generally having an elongated stem with a portion at one end, which is designed as a swab, spatula or a brush. However, drawbacks have been reported from these conventional techniques. The swab technique has the disadvantages

that the stick may break when abrasive force is applied to enable specimen sampling and extra time-consuming step is required to examine the mixing of desired and undesired cells on a microscope slide. In addition the cotton buds swab stick is also unsatisfactory in retaining and transferring of cellular samples due to its rather tightly-wound and very absorbent ball-like surface. It has also a very limited contact with the exocervix.

The spatula technique enables cell sampling even from deeper cell layers, however, such device may cause post-exam bleeding or abrasion at the sampling spot. In addition the wooden or plastic spatulas are too stiff and rigid to provide an even and thorough scraping of the unevenly contoured uterine cervix. It is also less efficient in transferring the cellular samples onto the glass slides due to its inflexible L-shaped end portion.

Cellular samples obtained by the brush technique are usually overly blood-stained and a fair number of critical cervical cells are being trapped in between the bristles and hence do not get transferred fully onto the glass slides and therefore are wasted and lost for diagnosis. The brush device has also a very limited contact with the exocervix.

Summary of the Invention

The primary object of this invention is to provide a new and improved cell sampler to collect representative cell samples from the exocervix and endocervix for cytological microscopic examination. It involves only a simple "one-step" operation where a single insertion into the cervical canal can obtain both exocervical and endocervical cell samples.

Another object of this invention is to provide a cell sampler that holds securely at the exocervix and prevent excessive penetration into the internal os.

Still another object of this invention is to provide a cell sampler having an endocervical contact portion that is safe in use, thereby provides more comfort and less abrasive when making a complete 360 DEG rotational sweeping-up of all the representative cells.

Yet another object of this invention is to provide a cell sampler that is capable of collecting cells from deep inside body cavities due to the semi rigid vertical reach of the endocervical contact portion.

A further object of this invention is to provide a cell sampler that allows combined yet separated cell samples from both exocervical and endocervical regions with just a single swipe onto a microscope slide where these cellular portions are clearly visible.

A still further object of this invention is to provide a cell sampler having a slightly thickened-handle to enhance better finger grip and optimal rotational manipulation.

These and further objects, features and advantages of the present invention will become apparent from the following description when taken in connection with the accompanying drawings which, for purposes of illustration only, show the preferred embodiment in accordance with the present invention.

Brief Description of the Drawings

FIG. 1 is a perspective view of the present cell sampler for sampling purpose.

FIG. 2 is a perspective view of the present cell sampler for spreading purpose.

FIG. 3 illustrates the transfer of samples onto a microscope slide.

FIG. 4 illustrates the rotational mechanism of the vertical contact portion of the present cell sampler.

Detailed Description of the Invention

With reference to the figure 1, the drawing shows in embodiment comprises an elongated and rounded stick-shaped stem (1) having a slightly thickened handle means (2) at bottom end to enhance better finger grip and optimal rotational manipulation. At the top end of said stem (1) is connected to an abrading means (3). The said abrading means (3) comprises a connecting means (4) and a functional L-shaped cell collecting means (5). The functional L-shaped cell collecting means (5) comprising of a vertical ENDOcervical contact portion (6) therein to aid in insertion of said cell sampler into the endocervix and configured to scrape cytology cell samples onto its surface when said cell sampler is rotated; and a horizontal EXOcervical contact portion (7) therein to aid in hugging the exocervix and scraping cytology cell samples onto its surface when said cell sampler is rotated.

The said vertical endocervical contact portion (6) is connected to the horizontal exocervical contact portion (7) by attachment means, preferably a predetermined, semi-tightened ball joint thus allowing the said vertical contact portion to has a 90 degree free moving angle with the respect to the horizontal exocervical contact portion (7) as shown in figure 4. The vertical endocervical contact portion (6) can stay critically upright while performing its cell sampling rotational scraping function and also enable to made instantly collapsible to a horizontal position onto microscope slide with just very slight finger pressure thus accomplishing its excellently designed objective of spreading the exo/endocervical cells speedily, smoothly and easily onto a microscope slide without the slightest hindrances. The attachment means also could be any fasteners, screws, snaps, clamps, clips, nuts or other such equivalents that could used to secure one surface to another and rotational movements with respect to the horizontal exocervical contact portion (7) are allowed.

The connecting means (4) having one end which is connected to said stem (1) is rounded in cross sectional shape and the other end is a flattened end. Supported one top of the said flattened end is said functional L-shaped cell collecting means (5). The said flattened end

of the connecting means (4) comprising of a supporting protrusion (8) at one edge of said flattened end and a retaining protrusion (9) at the other edge of said flattened end. The said EXOcervical contact portion (7) is attached to the supporting protrusion (8) of said connecting means (4).

The functional L-shaped cell collecting means (5) is coated with resilient material such as sponge, foam, fibre, silicon, PVC film, rubber, soft plastics and the like, thereby provide more comfort and less abrasive, yet direct and gently hugging to the critical transformation zone (T-zone), thereby allowing a thorough and complete 360 DEG rotational sweeping-up of all the truly representative cells. The retaining protrusion (9)of said connecting means (4) being configured to prevent excessive penetration of said cell sampler into the endocervix and lend resistance to the collapsible of said vertical ENDOcervical contact portion (6).

Figure 2 shows a flattened portion of EXOcervical and ENDOcervical contact portions. After a smear sample has been taken from the cervical canal, the said cell sampler is withdrawn from the cervix and the vertical ENDOcervical contact portion (6) will immediately be bent and collapsed on top of a microscope slide (10) as shown

in figure 3, becoming a horizontal, straight and flat spreading strip to be gently swept across the full length of the microscope slide (10), demonstrating clearly a combined yet separated cellular portions from both the exocervical and endocervical regions.

The invention is advantageously for use in a simple "one-step" operation involving only a single insertion for sampling cells from exocervix and endocervix and obtain representative cells from both regions to be included on the same microscope slide.

It is to be understood that the present invention may be embodied in other specific forms and is not limited to the sole embodiment described above. However modification and equivalents of the disclosed concepts such as those which readily occur to one skilled in the art are intended to be included within the scope of the claims which are appended thereto.

CLAIMS

1) A sampler for sampling cervical cells comprising of;
an elongate handle;
first collecting means attached to one end of said handle for hugging the exocervix and scraping cytology cell samples;
second collecting means attached to first collecting means for collecting cytology cell samples from the endocervix area;
wherein said first and second collecting means are pivotally connected.

2) A sampler as claimed in claim 1 wherein the first and second collecting means each have a resilient surface to collect the cell samples.

3) A sampler as claimed in claim 1 wherein the first and second collecting means each have a bristle surface to trap the cell samples.

4) A sampler as claimed in claims 2 and 3 wherein the surfaces are made of polymeric material.

5) A sampler as claimed in Claim 2 and 3 wherein the resilient surface is made of sponge, foam or fibre.

6) A sampler as claimed as claim 1 wherein when in collecting position the first collecting means is substantially right angle with the second collecting means.

7) A sampler as claimed in claim 1 wherein when in smearing position the surfaces of the first and second collecting means are in the same plane to enable a wider spread of the collected cell samples onto microscope slide.

8) A sampler as claimed in claim 7 wherein in smearing position the end of handle adjacent the second collecting means has a slight extension to prevent the said second collecting means from pivoting beyond the same planar as the first collecting means.

9) A cell sampler which includes a handle, first collecting means attached to one end of said handle for hugging the exocervix and scraping cytology cell samples, second collecting means pivotly attached to first collecting means for collecting cytology cell samples from the endocervix area;

characterised in that;

said first and second collecting means are pivotally connected so as to be movable relatively to one another between smearing position in which they are generally L- shaped configuration and a smearing position in which they are in a straight line.

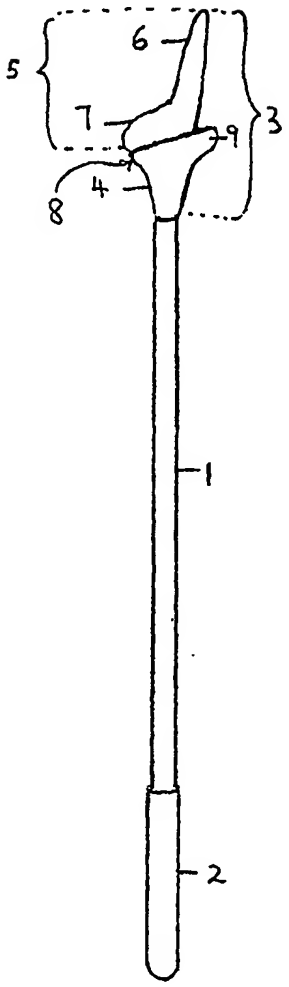

FIG. 1

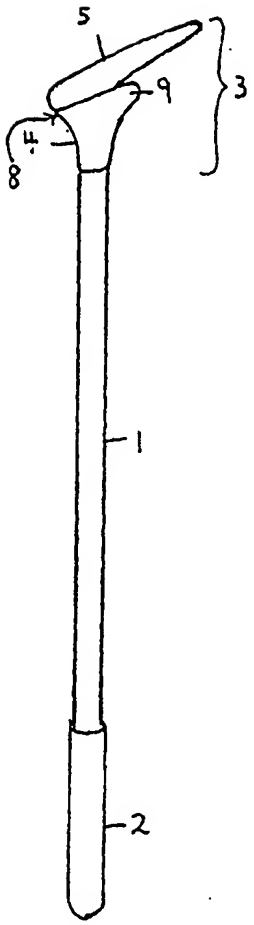

FIG. 2

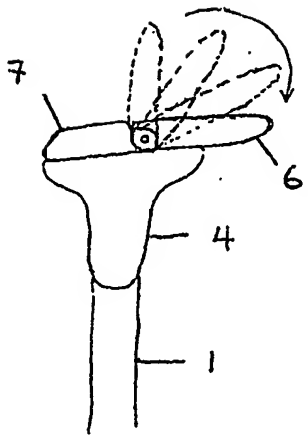

FIG 4

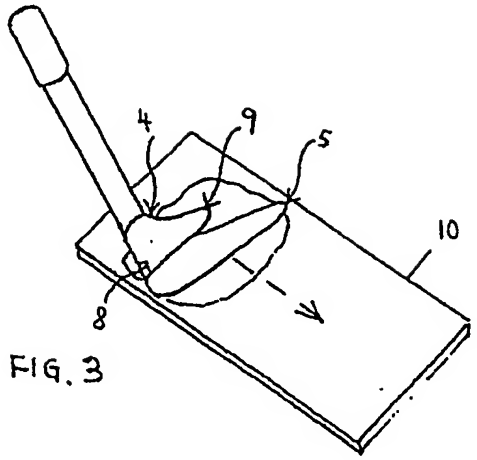

FIG. 3

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
11347MY1/SKL/LLX		
International application No.	International filing date (*day/month/year*)	(Earliest) Priority Date (*day/month/year*)
PCT/SG 2003/000153	21 June 2003 (21.06.2003)	21 June 2002 (21.06.2002)
Applicant		
MOO YOON NGEN PI		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
      ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:
      ☐ contained in the international application in written form.
      ☐ filed together with the international application in computer readable form.
      ☐ furnished subsequently to this Authority in written form.
      ☐ furnished subsequently to this Authority in computer readable form.
      ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
      ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
2. ☐ **Certain claims were found unsearchable** (See Box I).
3. ☐ **Unity of invention is lacking** (See Box II).
4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract**,
   ☐ the text is approved as submitted by the applicant.
   ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the **drawings** to be published with the abstract is Figure No.: 1&4
   ☐ as suggested by the applicant. ☐ None of the figures.
   ☐ because the applicant failed to suggest a figure.
   ☒ because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG 03/00153-0

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

An L-shaped, precision contoured EXO/ENDOcervical cell sampler for collecting representative cells is invented for pre-malignant and malignant diagnosis. The said cell sampler comprises of an elongated and rounded stick-shaped stem (1) with a slightly thickened handle means (2) at one end, and a flattened connecting means (4) having two protrusions (8,9) at the other end. An L-shaped configuration (5) at the root of said connecting means (4) has one vertical ENDOcervical contact portion (6) and one horizontal EXOcervical contact portion (7), which directly hug to the transformation zone thereby allowing a through and complete 360 DEG rotatinal sweeping-up of all the truly representatives cells. When said cell sampler is withdrawn from the cervix, the vertical ENDOcervical contact portion (6) is subsequently bent and both the EXO-and ENDOcervical portions are swept across a microscope slide (10) for cytological microscopic examination.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG 03/00153-0

CLASSIFICATION OF SUBJECT MATTER

IPC[7]: A61B 10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC[7]: A61B 10/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0527909 B1 (MEDSCAND AB) 24 November 1993 (24.11.1993) *the whole document; especially fig. 1-8; column 3, lines 14-28; column 4, line 1 - column 6, line 36; claims 1,2,5,9.*	1-7,9
A	EP 0864296 A1 (LAB. C.C.D.) 16 September 1998 (16.09.1998) *fig. 1,2; abstract; column 4, lines 49-51.*	1,3,4,6
A	US 6346086 B1 (J. Maksem et al.) 12 February 2002 (12.02.2002) *fig. 5,10; abstract; column 10, line 49 - column 11, line 15; column 11, line 52 - column 12, line 22.*	1,4,5
A	US 5279307 A (R. Mohajer) 18 January 1994 (18.01.1994) *the whole document.*	1-4,6
A	US 5022408 A (R. Mojaher) 11 June 1991 (11.06.1991) *the whole document.*	1-4,6

☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
„A" document defining the general state of the art which is not considered to be of particular relevance
„E" earlier application or patent but published on or after the international filing date
„L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
„O" document referring to an oral disclosure, use, exhibition or other means
„P" document published prior to the international filing date but later than the priority date claimed
„T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
„X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
„Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
„&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 March 2004 (31.03.2004)	24 June 2004 (24.06.2004)
Name and mailing adress of the ISA/AT Austrian Patent Office Dresdner Straße 87, A-1200 Vienna Facsimile No. 1/53424/535	Authorized officer LUDWIG H. Telephone No. 1/53424/340

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG 03/00153-0

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5623941 (T. Hedberg et al.) 29 April 1997 (29.04.1997) *the whole document; especially fig. 4,8,16; column 3, lines 16-22; column 4, lines 7-18,28-36, column 5, lines 48-53; claims 1,3.*	1,3-5

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/SG 03/00153-0

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP A 527909		ES T 2046897T	1994-02-01
		WO A 9116855	1991-11-14
		SE A 9001679	1991-09-16
		SE B 465451	1991-09-16
		EP A 0527909	1993-02-24
		DE T 69100688T	1994-05-05
EP A 864296		FR A 2760626	1998-09-18
		EP A 0864296	1998-09-16
US A 5022408	1991-06-11	JP T 5507634T	1993-11-04
		BR A 9106373	1993-04-27
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